NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Specialist Adviser questionnaire

Before completing this questionnaire, please read Conflicts of Interest for Specialist Advisers. Certain conflicts exclude you from offering advice, however, please return the questionnaire to us incomplete for our records.

Please respond in the boxes provided.

Please complete and return to: tristan.mckenna@nice.org.uk

Procedure Name: IP1506 Endoscopic full thickness removal of non-lifting colonic adenoma

Name of Specialist Advisor: Dr. Praful Patel

Specialist Society: **British Society of Gastroenterology (BSG)**

1 Do you have adequate knowledge of this procedure to provide advice?

x Yes.

☐ No – please return the form/answer no more questions.

1.1 Does the title used above describe the procedure adequately?

☐ Yes.

x No. If no, please enter any other titles below.

Comments:

Endoscopic full thickness resection of colonic polyp

This is more appropriate as this technique allows resection other types of polyps besides adenomas and those that are non-lifting but cannot be removed by conventional endoscopic EMR/ESD technique and would otherwise be subject to surgical resection. Examples include early cancer polyps, sub-mucosal polyps like neuro-endocrine tumours and benign polyps at the appendix or diverticulum.

2 Your involvement in the procedure

2.1 Is this procedure relevant to your specialty?

x Yes.

☐ Is there any kind of inter-specialty controversy over the procedure?

☐ No. If no, then answer no more questions, but please give any information you can about who is likely to be doing the procedure.

Comments:

This will be relevance to endoscopists both medical and surgical

The next 2 questions are about whether you carry out the procedure, or refer patients for it. If you are in a specialty that normally carries out the procedure please answer question 2.2.1. If you are in a specialty that normally selects or refers patients for the procedure, please answer question 2.2.2.

2.2.1 If you are in a specialty that does this procedure, please indicate your experience with it:

☐ I have never done this procedure.

☐ I have done this procedure at least once.

x I do this procedure regularly.

Comments:

At Southampton , we were the first to carry out the procedure in the UK and have the done most cases in the UK - 16 of 26 cases out of 6 centres so far and are doing 3 cases every month. We also teach other consultants on the only FRTD UK course -3 so far in the last year.

2.2.2 If your specialty is involved in patient selection or referral to another specialty for this procedure, please indicate your experience with it.

☐ I have never taken part in the selection or referral of a patient for this procedure.

☐ I have taken part in patient selection or referred a patient for this procedure at least once.

x I take part in patient selection or refer patients for this procedure regularly.

Comments:

At Southampton, patients deemed suitable for FTRD are referred from local colleagues or regionally and all discussed in the colorectal MDT and counselling of patient before treatment is offered.

2.3 Please indicate your research experience relating to this procedure (please choose one or more if relevant):

x I have done bibliographic research on this procedure.

☐ I have done research on this procedure in laboratory settings (e.g. device-related research).

x I have done clinical research on this procedure involving patients or healthy volunteers.

☐ I have had no involvement in research on this procedure.

☐ Other (please comment)

Comments:

I have carried out case series in the procedure in pig model and human cases, with first UK presentation of results at BSG 2016 and published as an abstract.

3 Status of the procedure

3.1 Which of the following best describes the procedure (choose one):

☐ Established practice and no longer new.

x A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.

x Definitely novel and of uncertain safety and efficacy.

☐ The first in a new class of procedure.

Comments:

For the purpose of polyp removal it is novel, over 1000 procedures have been carried out internationally – mostly in Germany and we have outcome and safety data on these series of patient which suggests good safety and efficacy. In Germany the procedure is being carried out routinely in tertiary centres.
This could be interpreted as a minor variation to existing procedure by the same company called IVESCO clip which is a full thickness endoscopic clipping device and used for closing stomach and bowel perforations, fistulae and large bleeding.

3.2 What would be the comparator (standard practice) to this procedure?

Mainly laparoscopic but also open bowel resection

3.3 Please estimate the proportion of doctors in your specialty who are doing this procedure (choose one):

☐ More than 50% of specialists engaged in this area of work.

☐ 10% to 50% of specialists engaged in this area of work.

x Fewer than 10% of specialists engaged in this area of work.

☐ Cannot give an estimate.

Comments: Only 6 centres current doing this currently, but expect that this will increase substantially in 2017.

4 Safety and efficacy

4.1 What is the potential harm of the procedure?

Please list adverse events and major risks (even if uncommon) and, if possible, estimate their incidence, as follows:

1. Adverse events reported in the literature (if possible please cite literature)

Reported in publications below are minor bleeding 4%, post-polypecomy syndrome 8 %, clipping, however data for German registry subsequently show possibility of perforation around 1% and appendicitis and small bowel clipping <1%.

Reference : Endoscopic full thickness resection in the colorectum with novel over the scope device: first experience. Aurther Schmidt et al. Endoscopy 2015 : 10.1055/s-0034-1391781

2. Anecdotal adverse events (known from experience)

No significant adverse events except 1 case of in ability to capture polyp in snare at time of resection after clipping. Polyp was removed using another snare.

3. Theoretical adverse events

There is the possibility of clip failure but whether transpires will come in larger case series

4.2 What are the key efficacy outcomes for this procedure?

R0 resection – 75%
Avoiding surgery – 80%

4.3 Are there uncertainties or concerns about the *efficacy* of this procedure? If so, what are they?

There are no randomised controlled trials with surgery so far but these are not always necessary to show effectiveness as has occurred with endoscopic EMR of polyps.

4.4 What training and facilities are needed to do this procedure safely?

1 day theoretical and pig-mode practical teaching day for trained expert endoscopists already performing EMR/ESD followed by mentorship of initial cases by trained experienced FTRD endoscopist. This procedure should be carried out in hospital where immediate therapeutic endoscopy and surgery is available in case of complications. Propfol/GA facilities may be required.

4.5 Are there any major trials or registries of this procedure currently in progress? If so, please list.

In Germany - WALL- RESECT trial NCT02362126. There is a large European registry and Dr. Praful Patel in Southampton has set up the UK registry

4.6 Are you aware of any abstracts that have been *recently* presented/ published on this procedure that may not be listed in a standard literature search, for example PUBMED? (This can include your own work). If yes, please list.
Please note that NICE will do a literature search: we are only asking you for any very recent or potentially obscure abstracts and papers. Please do not feel the need to supply a comprehensive reference list (but you may list any that you think are particularly important if you wish).

1. **Endoscopic full thickness resection (EFTR) in the colon with the FTRD system: The first UK experience**. *I Rahman, P. Boger P. Patel et al.* Gut 2016;**65**:A9-A10
2. **Endoscopic full-thickness resection of colorectal neoplasias: Report on the first Dutch experience** *Strebus J, Hageman L, van der Speck BW and Heine GDN,* Alkmaar, The Netherlands, and Haverkort ME, Haaglanden, The Netherlands (2016) Spring meeting of the Dutch Society for Gastroenterology, March 17 and 18, 2016, Koningshof Veldhoven, The Netherlands
3. **Resection of rectal carcinoids with the newly introduced endoscopic full-thickness resection device** *Grauer M, Gschwendtner A, Schäfer C, Neumann H* Endoscopy. 2016;48 Suppl 1:E123-4. doi: 10.1055/s-0042-104651. Epub 2016 Mar 23. PubMed PMID: 27008564.
4. **Endoscopic full-thickness resection of adenoma in colon** *Bulut M, Gögenur I, Hansen LB* Ugeskr Laeger. 2015 Dec 21;177(52). pii: V07150589. Danish. PubMed PMID: 26692224.
5. **Full Thickness Resection Device - Eine neue Methode zur endoskopischen Vollwandresektion im Kolorektum** *Kratt T, Zerabruck E, Königsrainer A, Götz M, Baur F, Gubler C, Bauerfeind P, Fried M, Caca K, Schmidt A* Der Gastroenterologe, **Neue Techniken,** January 2015, Volume 10, Issue 1, pp 39-42
6. **Die flexibel-endoskopische Vollwandresektion im GI-Trakt: Neuentwicklung und erste klinische Erfahrungen mit dem FTRD-System (full-thickness resection device)** *Kratt T, Kirschniak A, Schenk M, Königsrainer A* Deutsche Gesellschaft für Chirurgie. 131. Kongress der Deutschen Gesellschaft für Chirurgie. Berlin, 25.-28.03.2014. Düsseldorf: German Medical Science GMS Publishing

House; 2014. Doc14dgch097 doi: 10.3205/14dgch097, urn:nbn:de:0183-14dgch097

7. **Neuentwicklung einer endoskopischen Vollwand-Resektionstechnik im GI-Trakt: erste klinische Erfahrungen mit dem FTRD-System** *Kratt T, Kirschniak A, Königsrainer A* http://www.mcn-nuernberg.de/vbc2013/90vbc-abstracts/I_01_Allgem_00093.pdf

4.7 Is there controversy, or important uncertainty, about any aspect of the way in which this procedure is currently being done or disseminated?

As a new procedure it will be important for NICE to give advice as soon as possible as it will allow a better, more co-ordinated and informed process to be followed in safely employing this new technique.

5 Audit Criteria

Please suggest a minimum dataset of criteria by which this procedure could be audited.

5.1 Outcome measures of benefit (including commonly used clinical outcomes, both short and long - term; and quality-of-life measures):

R0 resection , full thickness resection, diameter size of resection, time for procedure, avoidance of surgery.

5.2 Adverse outcomes (including potential early and late complications):

Perforation, bleeding, infection, post-polypectomy syndrome, appendicitis/diverticulitis, clipping of other organs, clip failure.

6 Trajectory of the procedure

6.1 In your opinion, how quickly do you think use of this procedure will spread?

Rapid increase in the next 1-2 years, then small steady rise.

6.2 This procedure, if safe and efficacious, is likely to be carried out in (choose one):

☐ Most or all district general hospitals.

x A minority of hospitals, but at least 10 in the UK.

☐ Fewer than 10 specialist centres in the UK.

☐ Cannot predict at present.

Comments:

It is possible that many but not most hospital will do this procedure

6.3 The potential impact of this procedure on the NHS, in terms of numbers of patients eligible for treatment and use of resources, is:

x Major.

☐ Moderate.

☐ Minor.

Comments:
Although the numbers may not be high, there will be a significant proportion of patients with difficult polyps that may benefit from this procedure and it has the potential to replace many surgical resections in cases where polyps are not removable by conventional endoscopic techniques and therefore has potential to have major cost-benefits.

7 Other information

7.1 Is there any other information about this procedure that might assist NICE in assessing the possible need to investigate its use?

8 Data protection and conflicts of interest

8. Data protection, freedom of information and conflicts of interest

8.1 Data Protection

The information you submit on this form will be retained and used by the NICE and its advisers for the purpose of developing its guidance and may be passed to other approved third parties. Your name and specialist society will be published in NICE publications and on the NICE website. The specialist advice questionnaire will be published in accordance with our guidance development processes and a copy will be sent to the nominating Specialist Society. Please avoid identifying any individual in your comments.

X I have read and understood this statement and accept that personal information sent to us will be retained and used for the purposes and in the manner specified above and in accordance with the Data Protection Act 1998.

8.2 Declarations of interest by Specialist Advisers advising the NICE Interventional Procedures Advisory Committee

Nothing in your submission shall restrict any disclosure of information by NICE that is required by law (including in particular, but without limitation, the Freedom of Information Act 2000).

Please submit a conflicts of interest declaration form listing any potential conflicts of interest including any involvement you may have in disputes or complaints relating to this procedure.

Please use the "Conflicts of Interest for Specialist Advisers" policy as a guide when declaring any conflicts of interest. Specialist Advisers should seek advice if needed from the Associate Director – Interventional Procedures.

Do you or a member of your family[1] have a **personal pecuniary** interest? The main examples are as follows:

Consultancies or directorships attracting regular or occasional payments in cash or kind	☐	**YES**
	X	**NO**
Fee-paid work – any work commissioned by the healthcare industry **– this includes income earned in the course of private practice**	☐	**YES**
	X	**NO**
Shareholdings – any shareholding, or other beneficial interest, in shares of the healthcare industry	☐	**YES**
	X	**NO**
Expenses and hospitality – any expenses provided by a healthcare industry company beyond those reasonably required for accommodation, meals and travel to attend meetings and conferences	☐	**YES**
	X	**NO**
Investments – any funds that include investments in the healthcare industry	☐	**YES**
	X	**NO**
Do you have a **personal non-pecuniary** interest **–** for example have you made a public statement about the topic or do you hold an office in a professional organisation or advocacy group with a direct interest in the topic?	**X**	**YES**
	☐	**NO**

Do you have a **non-personal** interest? The main examples are as follows:

Fellowships endowed by the healthcare industry	☐	**YES**
	X	**NO**
Support by the healthcare industry or NICE that benefits his/her position or department, eg grants, sponsorship of posts	☐	**YES**
	X	**NO**

If you have answered YES to any of the above statements, please describe the nature of the conflict(s) below.

Comments:
I have trained others in the procedure under courses set up by the manufacturer/distributer and set up a national registry

Thank you very much for your help.

Dr Tom Clutton-Brock, Interventional Procedures Advisory Committee Chair

Professor Carole Longson, Director, Centre for Health Technology Evaluation.

Jan 2016

[1] 'Family members' refers to a spouse or partner living in the same residence as the member or employee, children for whom the member or employee is legally responsible, and adults for whom the member or employee is legally responsible (for example, an adult whose full power of attorney is held by the individual).

Conflicts of Interest for Specialist Advisers

1 Declarations of interest by Specialist Advisers advising the NICE Interventional Procedures Advisory Committee

1.1 Any conflicts of interest set out below should be declared on the questionnaire the Specialist Adviser completes for the procedure.

1.2 Specialist Advisers should seek advice if required from the Associate Director – Interventional Procedures.

2 **Personal pecuniary interests**

2.1 A personal pecuniary interest involves a current personal payment to a Specialist Adviser, which may either relate to the manufacturer or owner of a product or service being evaluated, in which case it is regarded as **'specific'** or to the industry or sector from which the product or service comes, in which case it is regarded as **'non-specific'**. The main examples are as follows.

2.1.1 **Consultancies** – any consultancy, directorship, position in or work for the healthcare industry that attracts regular or occasional payments in cash or kind (this includes both those which have been undertaken in the 12 months preceding the point at which the declaration is made and which are planned but have not taken place).

2.1.2 **Fee-paid work** – any work commissioned by the healthcare industry for which the member is paid in cash or in kind (this includes both those which have been undertaken in the 12 months preceding the point at which the declaration is made and which are planned but have not taken place).

2.1.3 **Shareholdings** – any shareholding, or other beneficial interest, in shares of the healthcare industry that are either held by the individual or for which the individual has legal responsibility (for example, children, or relatives whose full Power of Attorney is held by the individual). This does not include shareholdings through unit trusts, pensions funds, or other similar arrangements where the member has no influence on financial management.

2.1.4 **Expenses and hospitality** – any expenses provided by a healthcare industry company beyond that reasonably required for accommodation, meals and travel to attend meetings and conferences (this includes both those which have been undertaken in the 12 months preceding the point at which the declaration is made and which are planned but have not taken place.

2.1.5 **Investments** – any funds which include investments in the healthcare industry that are held in a portfolio over which individuals have the ability to instruct the fund manager as to the composition of the fund.

2.2 No personal interest exists in the case of:

2.2.1 assets over which individuals have no financial control (for example, wide portfolio unit trusts and occupational pension funds) and where the fund manager has full discretion as to its composition (for example, the Universities Superannuation Scheme)

2.2.2 accrued pension rights from earlier employment in the healthcare industry.

3 Personal family interest

3.1 This relates to the personal interests of a family member and involves a **current payment** to the family member of the Specialist Adviser. The interest may relate to the manufacturer or owner of a product or service being evaluated, in which case it is regarded as '**specific**', or to the industry or sector from which the product or service comes, in which case it is regarded as '**non-specific**'. The main examples include the following.

3.1.1 Any consultancy, directorship, position in or work for a healthcare industry that attracts regular or occasional payments in cash or in kind.

3.1.2 Any fee-paid work commissioned by a healthcare industry for which the member is paid in cash or in kind.

3.1.3 Any shareholdings, or other beneficial interests, in a healthcare industry which are either held by the family member or for which an individual covered by this Code has legal responsibility (for example, children, or adults whose full Power of Attorney is held by the individual).

3.1.4 Expenses and hospitality provided by a healthcare industry company (except where they are provided to a general class of people such as attendees at an open conference)

3.1.5 Funds which include investments in the healthcare industry that are held in a portfolio over which individuals have the ability to instruct the fund manager as to the composition of the fund.

3.2 No personal family interest exists in the case of:

3.2.1 assets over which individuals have no financial control (for example, wide portfolio unit trusts and occupational pension funds) and where the fund manager has full discretion as to its composition (for example, the Universities Superannuation Scheme)

3.2.2 accrued pension rights from earlier employment in the healthcare industry.

4 Personal non-pecuniary interests

These might include, but are not limited to:

4.1 a clear opinion, reached as the conclusion of a research project, about the clinical and/or cost effectiveness of an intervention under review

4.2 a public statement in which an individual covered by this Code has expressed a clear opinion about the matter under consideration, which could reasonably be interpreted as prejudicial to an objective interpretation of the evidence

4.3 holding office in a professional organisation or advocacy group with a direct interest in the matter under consideration

4.4 other reputational risks in relation to an intervention under review.

5 Non-personal interests

5.1 A non-personal interest involves payment that benefits a department or organisation for which a Specialist Advisor is responsible, but that is not received by the Specialist Advisor personally. This may either relate to the product or service being evaluated, in which case it is regarded as **'specific,'** or to the manufacturer or owner of the product or service, but is unrelated to the matter under consideration, in which case it is regarded as **'non-specific'**. The main examples are as follows.

5.1.1 **Fellowships** – the holding of a fellowship endowed by the healthcare industry.

5.1.2 **Support by the healthcare industry or NICE** – any payment, or other support by the healthcare industry or by NICE that does not convey any pecuniary or material benefit to a member personally but that does benefit his/her position or department. For example:

- a grant from a company for the running of a unit or department for which a Specialist Advisor is responsible
- a grant, fellowship or other payment to sponsor a post or member of staff in the unit for which a Specialist Adviser is responsible. This does not include financial assistance for students
- the commissioning of research or other work by, or advice from, staff who work in a unit for which the specialist advisor is responsible
- one or more contracts with, or grants from, NICE.

5.2 Specialist Advisers are under no obligation to seek out knowledge of work done for, or on behalf of, the healthcare industry within departments for which they are responsible if they would not normally expect to be informed.

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Specialist Adviser questionnaire

Before completing this questionnaire, please read Conflicts of Interest for Specialist Advisers. Certain conflicts exclude you from offering advice, however, please return the questionnaire to us incomplete for our records.

Please respond in the boxes provided.

Please complete and return to: tristan.mckenna@nice.org.uk

Procedure Name: IP1506 Endoscopic full thickness removal of non-lifting colonic adenoma

Name of Specialist Advisor: Mr Rahman

Specialist Society: **British Society of Gastroenterology (BSG)**

1 Do you have adequate knowledge of this procedure to provide advice?

☒ Yes.

☐ No – please return the form/answer no more questions.

1.1 Does the title used above describe the procedure adequately?

☒ Yes.

☐ No. If no, please enter any other titles below.

Comments:

2 Your involvement in the procedure

2.1 Is this procedure relevant to your specialty?

☒ Yes.

☐ Is there any kind of inter-specialty controversy over the procedure?

☐ No. If no, then answer no more questions, but please give any information you can about who is likely to be doing the procedure.

Comments:

The next 2 questions are about whether you carry out the procedure, or refer patients for it. If you are in a specialty that normally carries out the procedure please answer question 2.2.1. If you are in a specialty that normally selects or refers patients for the procedure, please answer question 2.2.2.

2.2.1 If you are in a specialty that does this procedure, please indicate your experience with it:

☐ I have never done this procedure.

☒ I have done this procedure at least once.

☐ I do this procedure regularly.

Comments: *I have undertaken this procedure 3 times in the UK but have done several cases ex-vivo. I am part of the teaching faculty that teaches this procedure on a UK course. Have met and discussed this procedure with German colleagues who have more extensive experience with this as well as review their audit data.*

2.2.2 If your specialty is involved in patient selection or referral to another specialty for this procedure, please indicate your experience with it.

☐ I have never taken part in the selection or referral of a patient for this procedure.

☒ I have taken part in patient selection or referred a patient for this procedure at least once.

☐ I take part in patient selection or refer patients for this procedure regularly.

Comments: *The process requires discussion of cases within a colorectal/complex polyp MDT with colorectal colleagues for appropriate case selection. The feasibility of the removal of a lesion on a patient can be discussed with more experienced users in the UK or easily accessible colleagues in Germany.*

2.3 Please indicate your research experience relating to this procedure (please choose one or more if relevant):

☒ I have done bibliographic research on this procedure.

☐ I have done research on this procedure in laboratory settings (e.g. device-related research).

☒ I have done clinical research on this procedure involving patients or healthy volunteers.

☐ I have had no involvement in research on this procedure.

☐ Other (please comment)

Comments: *Have collated all of the UK experience to formulate a registry, about 26 procedures carried out in the UK, of which the vast majority have been undertaken at University Hospital Southampton. Data has been presented at the British Society of Gastroenterology 2016 meeting.*

3 Status of the procedure

3.1 Which of the following best describes the procedure (choose one):

☐ Established practice and no longer new.

☒ A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.

☒ Definitely novel and of uncertain safety and efficacy.

☐ The first in a new class of procedure.

Comments: *This is a modification of the over the scope clip available from ovesco which is widely used in the UK for closures of defects. There has been modification done to the clip design as well as the incorporation of a snare to enable cautery excision of lesions in one process. The procedure is novel in the sense that the variation in the design has enabled it to be the only device currently available for endoscopic full thickness resections in the colon. However the safety and efficacy has now been established with a large volume of data emerging from Germany and beginning in the UK*

3.2 What would be the comparator (standard practice) to this procedure?

Laparoscopic wedge resection undertaken by colorectal surgeons is the ideal comparator but necessitates the use of valuable theatre space and time. These lesions would otherwise be attempted to be removed by several attempts at endoscopic mucosal dissection or more cumbersomely with the technique of endoscopic submucosal dissection.

3.3 Please estimate the proportion of doctors in your specialty who are doing this procedure (choose one):

☐ More than 50% of specialists engaged in this area of work.

☐ 10% to 50% of specialists engaged in this area of work.

☒ Fewer than 10% of specialists engaged in this area of work.

☐ Cannot give an estimate.

Comments:

There have been 6 institutions who have undertaken this procedure in the UK, with 2/3rds of procedure being undertaken at University Hospital Southampton.

4 Safety and efficacy

4.1 What is the potential harm of the procedure?

Please list adverse events and major risks (even if uncommon) and, if possible, estimate their incidence, as follows:

1. Adverse events reported in the literature (if possible please cite literature)

Minor bleeding 6%, perforation 2%, post polypectomy syndrome 4%, appendicitis (2 cases), inadvertent clipping of small bowel (1 case).

2. Anecdotal adverse events (known from experience)

Nil so far in UK, apart from technical failure of the snare device closing after clip deployment. This necessitated going back in with a standard snare and removing the polyp.

3. Theoretical adverse events

Clip failing to maintain the anastomosis.

4.2 What are the key efficacy outcomes for this procedure?

Successful full thickness resection
Successful complete resection of lesion (R0 specimen)

4.3 Are there uncertainties or concerns about the *efficacy* of this procedure? If so, what are they?

There has now been more than 500 cases done in Germany with efficacy data available from they're registry

4.4 What training and facilities are needed to do this procedure safely?

Endoscopist and Nursing staff will require to attend a 1 day training course which goes through the procedure, set up and patient selection. The Unit undertaking this

should have already endoscopist undergoing advanced EMR along with a colorectal team available if adverse events should occur. To start the procedure should be undertaken under the supervision of an anaesthetist as propofol sedation will be required.

4.5 Are there any major trials or registries of this procedure currently in progress? If so, please list.

Multicenter prospective trial currently being undertaken in Germany, led by Arthur Schmidt. "Endoscopic Full Thickness Resection in the Lower GI Tract With the "Full Thickness Resection Device" (WALL-RESECT) NCT02362126."

The UK is currently finalising a registry to collect this data.

4.6 Are you aware of any abstracts that have been *recently* presented/ published on this procedure that may not be listed in a standard literature search, for example PUBMED? (This can include your own work). If yes, please list.
Please note that NICE will do a literature search: we are only asking you for any very recent or potentially obscure abstracts and papers. Please do not feel the need to supply a comprehensive reference list (but you may list any that you think are particularly important if you wish).

Recent presentation at BSG 2016, *"Endoscopic full thickness resection (EFTR) in the colon with the FTRD system: The first UK experience." Gut 2016;**65**:A9-A10 doi:10.1136/gutjnl-2016-312388.13*

4.7 Is there controversy, or important uncertainty, about any aspect of the way in which this procedure is currently being done or disseminated?

It is important that the procedure is only undertaken by those currently accredited to do so by attendance on a training day. This is currently the practice that has occurred in the UK and it is important that this continues.

5 Audit Criteria

Please suggest a minimum dataset of criteria by which this procedure could be audited.

5.1 Outcome measures of benefit (including commonly used clinical outcomes, both short and long - term; and quality-of-life measures):

Technical success of procedure.
Confirmed full thickness resection.
Confirmed R0 resection achieved
Specimen size (diameter)
Procedural time

5.2 Adverse outcomes (including potential early and late complications):

Early: Perforation, bleeding, post polypectomy syndrome, inadvertent clipping of adjacent organs

Late: Bleeding, failure of clip and dehiscence of anastomosis

6 Trajectory of the procedure

6.1 In your opinion, how quickly do you think use of this procedure will spread?

Within 1 year

6.2 This procedure, if safe and efficacious, is likely to be carried out in (choose one):

☐ Most or all district general hospitals.

☒ A minority of hospitals, but at least 10 in the UK.

☐ Fewer than 10 specialist centres in the UK.

☐ Cannot predict at present.

Comments:

It is likely that the service will be centralised to 2 or 3 centres within each region/county to generate enough volume for each user.

6.3 The potential impact of this procedure on the NHS, in terms of numbers of patients eligible for treatment and use of resources, is:

☐ Major.

☒ Moderate.

☐ Minor.

Comments: *Currently a hospital which is doing advanced lower GI therapeutic endoscopy may generate between 2-4 cases a month. This could substantially grow with experience as the indications for this would mainly be for non-lifting polyps/polyps in difficult locations/early cancerous polyps/submucosal polyps. Hence up to 20% of polyps currently referred to a specialist therapeutic endoscopist may undertake this procedure. The infrastructure and resources are already available as this can be done in a standard endoscopy room with the aid of a supervising anaesthetist.*

7 Other information

7.1 Is there any other information about this procedure that might assist NICE in assessing the possible need to investigate its use?

Currently the lesions potentially to be removed using this technique, such as non-lifting adenomas/adenomas in difficult locations/early polyp cancers, require either repeated colonoscopic procedures which may be ineffective or even surgery. The procedure has a relative short learning curve and offers potential curative resection for a large proportion of patients. Expertise is growing and there is already a dedicating training course set up in the UK to aid with potential endoscopist to begin this procedure.

8 Data protection and conflicts of interest

8. Data protection, freedom of information and conflicts of interest

8.1 Data Protection

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✓☐ I have read and understood this statement and accept that personal information sent to us will be retained and used for the purposes and in the manner specified above and in accordance with the Data Protection Act 1998.

8.2 **Declarations of interest by Specialist Advisers advising the NICE Interventional Procedures Advisory Committee**

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Do you or a member of your family[1] have a **personal pecuniary** interest? The main examples are as follows:

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Do you have a **personal non-pecuniary** interest – for example have you made a public statement about the topic or do you hold an office in a professional organisation or advocacy group with a direct interest in the topic?	☐ **YES** ☒ **NO**

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If you have answered YES to any of the above statements, please describe the nature of the conflict(s) below.

Comments:

Thank you very much for your help.

Dr Tom Clutton-Brock, Interventional Procedures Advisory Committee Chair

Professor Carole Longson, Director, Centre for Health Technology Evaluation.

Jan 2016

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- the commissioning of research or other work by, or advice from, staff who work in a unit for which the specialist advisor is responsible
- one or more contracts with, or grants from, NICE.

5.2 Specialist Advisers are under no obligation to seek out knowledge of work done for, or on behalf of, the healthcare industry within departments for which they are responsible if they would not normally expect to be informed.

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Specialist Adviser questionnaire

Before completing this questionnaire, please read Conflicts of Interest for Specialist Advisers. Certain conflicts exclude you from offering advice, however, please return the questionnaire to us incomplete for our records.

Please respond in the boxes provided.

Please complete and return to: tristan.mckenna@nice.org.uk

Procedure Name: IP1506 Endoscopic full thickness removal of non-lifting colonic adenoma

Name of Specialist Advisor: Mr Stebbing

Specialist Society: **British Society of Gastroenterology (BSG)**

1 Do you have adequate knowledge of this procedure to provide advice?

✓ Yes.

☐ No – please return the form/answer no more questions.

1.1 Does the title used above describe the procedure adequately?

✓ Yes.

☐ No. If no, please enter any other titles below.

Comments:

2 Your involvement in the procedure

2.1 Is this procedure relevant to your specialty?

✓ Yes.

✓ Is there any kind of inter-specialty controversy over the procedure?

☐ No. If no, then answer no more questions, but please give any information you can about who is likely to be doing the procedure.

Comments:

A decision to perform such a procedure should not be made at the time of index colonoscopy but carefully considered with discussion through the colorectal MDT

The next 2 questions are about whether you carry out the procedure, or refer patients for it. If you are in a specialty that normally carries out the procedure please answer question 2.2.1. If you are in a specialty that normally selects or refers patients for the procedure, please answer question 2.2.2.

2.2.1 If you are in a specialty that does this procedure, please indicate your experience with it:

✓ I have never done this procedure.

☐ I have done this procedure at least once.

☐ I do this procedure regularly.

Comments:

2.2.2 If your specialty is involved in patient selection or referral to another specialty for this procedure, please indicate your experience with it.

✓ I have never taken part in the selection or referral of a patient for this procedure.

☐ I have taken part in patient selection or referred a patient for this procedure at least once.

☐ I take part in patient selection or refer patients for this procedure regularly.

Comments:

2.3 Please indicate your research experience relating to this procedure (please choose one or more if relevant):

✓ I have done bibliographic research on this procedure.

☐ I have done research on this procedure in laboratory settings (e.g. device-related research).

☐ I have done clinical research on this procedure involving patients or healthy volunteers.

✓ I have had no involvement in research on this procedure.

☐ Other (please comment)

Comments:

3 Status of the procedure

3.1 Which of the following best describes the procedure (choose one):

☐ Established practice and no longer new.

☐ A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.

✓ Definitely novel and of uncertain safety and efficacy.

☐ The first in a new class of procedure.

Comments:

3.2 What would be the comparator (standard practice) to this procedure?

The standard approach to treatment of a significant non-lifting polyp would be segmental resection including the draining lymph node field.

3.3 Please estimate the proportion of doctors in your specialty who are doing this procedure (choose one):

☐ More than 50% of specialists engaged in this area of work.

☐ 10% to 50% of specialists engaged in this area of work.

✓ Fewer than 10% of specialists engaged in this area of work.

☐ Cannot give an estimate.

Comments:

The majority of these endoscopic procedures are performed by gastroenterologists with an interest in advanced endoscopic practice. Some perform the procedure in conjunction with a surgeon performing laparoscopy at the same time to observe the outside of the bowel.

4 Safety and efficacy

4.1 What is the potential harm of the procedure?

Please list adverse events and major risks (even if uncommon) and, if possible, estimate their incidence, as follows:

1. Adverse events reported in the literature (if possible please cite literature)

Bleeding at time of procedure or delayed bleeding requiring transfusion or unplanned admission to hospital.

Perforation of bowel with necessity for unplanned admission or emergency surgery

2. Anecdotal adverse events (known from experience)

N/A

3. Theoretical adverse events

The commonest bleeding occurs within the lumen of the bowel but given that the procedure involves full thickness resection, there may be a risk of intra-peritoneal bleeding with delayed presentation.

4.2 What are the key efficacy outcomes for this procedure?

Histological confirmation of complete excision of lesion.
Standardised reporting of lesion histology.
Documented audit of complcations

4.3 Are there uncertainties or concerns about the *efficacy* of this procedure? If so, what are they?

It is possible to predict malignancy ahead of this procedure from the morphological appearances of the lesion at first endoscopy and/or a non-lifting sign during assessment. It is difficult/impossible to accurately predict the full depth of invasion. Even complete removal of a lesion, if malignant, leaves the node staging unknown as these have not been removed and may, therefore, represent significant under-treatment or require subsequent operative treatment .

4.4 What training and facilities are needed to do this procedure safely?

Lab/model based skills practice to become familiar with equipment and use.
Mentored/supervised practice for first few procedures.
Full endoscopy unit facilties and access to GI surgical support.

4.5 Are there any major trials or registries of this procedure currently in progress? If so, please list.

My understanding is that units providing this service hold local databases of case. I am not aware whether there is a comprehensive national dataset.

4.6 Are you aware of any abstracts that have been *recently* presented/ published on this procedure that may not be listed in a standard literature search, for example PUBMED? (This can include your own work). If yes, please list.
Please note that NICE will do a literature search: we are only asking you for any very recent or potentially obscure abstracts and papers. Please do not feel the need to supply a comprehensive reference list (but you may list any that you think are particularly important if you wish).

No

4.7 Is there controversy, or important uncertainty, about any aspect of the way in which this procedure is currently being done or disseminated?

The procedure should not be widely adopted unless good evidence confirms equivalent oncological outcomes for patients.
A national dataset would be ideal.

5 Audit Criteria
Please suggest a minimum dataset of criteria by which this procedure could be audited.

5.1 Outcome measures of benefit (including commonly used clinical outcomes, both short and long - term; and quality-of-life measures):

Histological confirmation of complete excision
Patient experience measures at time of procedure
Proportion of patients where this treatment alone is considered sufficient.
Proportion of patients requiring additional treatment eg. Repeat endoscopy or operative resection.
One and three-year relapse and disease-free survival for either benign or malignant histology

5.2 Adverse outcomes (including potential early and late complications):

Unplanned admission for bleeding or perforation
Relapse at site of primary treatment
Loco-regional or distant metastases following treatment of malignant lesion by this technique alone

6 Trajectory of the procedure

6.1 In your opinion, how quickly do you think use of this procedure will spread?

Enthusiasts/early adopters will develop practice over 1-2 years; majority will await substantive evidence of efficacy and safety.

6.2 This procedure, if safe and efficacious, is likely to be carried out in (choose one):

☐ Most or all district general hospitals.

✓ A minority of hospitals, but at least 10 in the UK.

☐ Fewer than 10 specialist centres in the UK.

☐ Cannot predict at present.

Comments:

6.3 The potential impact of this procedure on the NHS, in terms of numbers of patients eligible for treatment and use of resources, is:

☐ Major.

☐ Moderate.

✓ Minor.

Comments:
The volume of suitable cases will remain very low compared with the volume of patient undergoing standard polypectomy techniques

7 Other information

7.1 Is there any other information about this procedure that might assist NICE in assessing the possible need to investigate its use?

N/A

8 Data protection and conflicts of interest

8. Data protection, freedom of information and conflicts of interest

8.1 Data Protection

The information you submit on this form will be retained and used by the NICE and its advisers for the purpose of developing its guidance and may be passed to other approved third parties. Your name and specialist society will be published in NICE publications and on the NICE website. The specialist advice questionnaire will be published in accordance with our guidance development processes and a copy will be sent to the nominating Specialist Society. Please avoid identifying any individual in your comments.

☑ I have read and understood this statement and accept that personal information sent to us will be retained and used for the purposes and in the manner specified above and in accordance with the Data Protection Act 1998.

8.2 **Declarations of interest by Specialist Advisers advising the NICE Interventional Procedures Advisory Committee**

Nothing in your submission shall restrict any disclosure of information by NICE that is required by law (including in particular, but without limitation, the Freedom of Information Act 2000).

Please submit a conflicts of interest declaration form listing any potential conflicts of interest including any involvement you may have in disputes or complaints relating to this procedure.

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✓ **NO**

If you have answered YES to any of the above statements, please describe the nature of the conflict(s) below.

Comments:
I am a Trustee of the national charity Bowel Cancer UK

Thank you very much for your help.

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